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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,975	11/17/2003	Scott T. Latterell	LIFE-089CON3	5343

24353 7590 12/29/2004

BOZICEVIC, FIELD & FRANCIS LLP
1900 UNIVERSITY AVE
SUITE 200
EAST PALO ALTO, CA 94303

EXAMINER

TOOR, SADAF A

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Office Action Summary</p>	Application No. 10/715,975		Applicant(s) LATTERELL ET AL.	
	Examiner Sadaf Toor		Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 11-31 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/17/2003</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities:
 - a. Inconsistent terminology referring to part 50 on page 8. Lines 7-8 refer to “enlarged cylindrical portion 50” and lines 15-16 refer to “enlarged diameter portion 50.”
 - b. Inconsistent terminology referring to part 75 on page 9. Line 18 refers to “distal end 75” and lines 26-27 refer to “base end 75.”
 - c. Inconsistent terminology referring to part 102 on page 10. Lines 24-25 refer to “forward sampling portion 102” and lines 26-27 (as well as page 11, line 7) refer to “sampling end 102.”
 - d. Inconsistent terminology referring to part 12 on page 11. Line 11 refers to “absorbent material 12” and lines 15-16 refer to “membrane 12.”
 - e. Inconsistent terminology referring to part 114 on page 11. Line 31 refers to “lever arm 114” and lines 32-33 refer to “lever member 114.”
 - f. Inconsistent terminology referring to part 116 on page 12. Line 1 refers to “latching end 116” and line 7 refers to “locking end 116.”

Applicant is reminded to use consistent terminology when referring to the parts of the invention and encouraged to check the description for other similar errors. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31 recites the limitation "said skin stretching member" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 11-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,712,776.

Regarding claims 11-23, although the conflicting claims are not identical, they are not patentably distinct from each other because both the claims of the patent and the present application recite methods for collecting a sample of body fluid from a skin layer and have substantially equivalent method steps. The subject matter of claims 11-14 of the present application generally corresponds to that of claims 1-4 of the patent. Claims 15-17 of the present application are substantially equivalent to claims 9-11 of the patent. Claims 18-20 of the present application are substantially equivalent to claims 5-7 of the patent. Claims 21, 22, and 23 of the present application generally correspond to claims 12, 8, and 13 of the patent respectively.

Regarding claims 24-31, although the conflicting claims are not identical, they are not patentably distinct from each other because the method steps for collecting a sample of body fluid from skin layer recited in the patent provide a sampling tool for accessing a sample of body fluid from a skin layer as recited in the claims of the present application. The subject matter of claims 24-25 of the present application generally corresponds to that of claim 1 of the patent. Claims 27, 28, and 29 of the present application are substantially equivalent to claims 2, 4, and 8 of the patent respectively. The subject matter of claim 29 of the present application generally corresponds to that of claim 9 of the patent. Claims 30-31 of the present application are substantially equivalent to claims 5 and 8 of the patent.

Conclusion

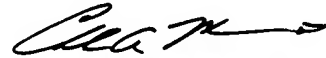
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sadaf Toor whose telephone number is (571) 272-4734. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

Art Unit: 3736

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sat
12/22/04


CHARLES MARMOR
PRIMARY EXAMINER